K063110

510(k) Summary
As Required by 21 section 807.92 (c)

OCT 26 2006

1-Submitter Name: SHANGHAI DENTAL INSTRUMENT FACTORY CO., LTD ("SDIF")
2-Address: 820 LINGSHI ROAD, SHANGHAI CHINA 200072
3-Phone: Tel +86 21 66255988.
4-Fax: Fax +86 21 56956197
5-Contact Person: Ms Chen Yimei, Vice General Manager
6- Consultant: Jay Mansour, Mansour Consulting LLC, 845 Aronson Lake Court, Roswell, GA 30075 USA. Tel 678-908-8180. Fax 678-623-3765
7-Date summary prepared: October 24th, 2006
8-Device Trade or Proprietary Name: CST61 high speed turbine handpiece
9-Device Common or usual name: high speed turbine handpiece
10-Device Classification Name: handpiece, air-powered, dental
11-Substantial Equivalency is claimed against the following device: K022535

12-Description of the Device:

CST61 high speed turbine handpiece is an air-powered, hand-held device for use as an operative dental unit accessory at 250KPa with rotation speed of 250,000 RPM in order to perform cutting, shaping, grinding, and polishing functions.

13-Intended use of the device: (refer to FDA forms attached)

CST61 high speed turbine handpiece is intended for use intra and extra orally to cut, shape, grind and polish teeth, or items related to teeth and dental devices that may be in the mouth or to be placed in the mouth.

14-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

15-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. **Refer to the explanations within the main submission.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shanghai Dental Instrument factory
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, Minnesota 55313

OCT 26 2006

Re: K063110
Trade/Device Name: CST61 High Speed Turbine Handpiece
Regulation Number: 872.4200
Regulation Name: Dental Handpiece Accessories
Regulatory Class: I
Product Code: EFB
Dated: October 9, 2006
Received: October 11, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

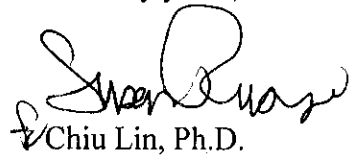
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063110

Device Name: CST61 HIGH SPEED TURBINE HANDPIECE

Indications For Use:

CST61 High Speed Turbine Handpiece is indicated for use intra and extra orally to cut, shape, grind and polish teeth, or items related to teeth and dental devices that may be in the mouth or to be placed in the mouth

Prescription Use ✔ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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